Bard® E•LUMINEXX™ Biliary Stent

510(k) Summary of Safety and Effectiveness

MAY 3 0 2008

21 CFR 807.92(a).

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug, and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based as follows:

General Information:

Submitter Name:	Bard Peripheral Vascular, Inc.
Address:	1625 W. Third Street P.O. BOX 1740 Tempe, AZ 85280-1740
Telephone Number:	(480) 894-9515
Fax Number:	(480) 449-2546
Contact Person:	Lindsay K. Pack Regulatory Affairs Specialist

Device Information:

Device Trade Name:	**E•LUMINEXX™ Biliary Stent**
Common/Usual Name:	Biliary Stent
Classification:	Class II
Classification Panel:	Gastroenterology/Urology Devices Panel

Predicate Device:

LUMINEXX® 3 Biliary Stent (K033497 on February 4, 2004)

Summary of Change:

The modification to the E•LUMINEXX™ Biliary Stent is an electropolished surface finish. These changes result in a subject device that has an improved surface finish, smoother edges, and improved corrosion resistance. All other aspects of the subject device remain the same as the predicate device.

Device Description:

The Bard® E•LUMINEXX™ Biliary Stent is a stenting device designed to maintain the patency of biliary ducts obstructed by malignant neoplasms. The device includes the

self-expanding nitinol E•LUMINEXX™ Stent preloaded on a flexible, multifunctional stent deployment system, the BARD S.A.F.E.™ Delivery System with the PerforMAXX™ Grip. It is preloaded into the delivery system and is available in two delivery system lengths, and various device diameters and lengths.

Intended Use of Device:

The Bard® E• LUMINEXX™ Biliary Stent is intended for palliation of malignant strictures in the biliary tree.

Technological Comparison to Predicate Device:

The technological characteristics of E•LUMINEXX™ Biliary Stent are substantially equivalent to those of the predicate LUMINEXX® 3 Biliary Stent in terms of intended use, application, patient population, basic design, performance, contraindications, materials, and sterilization method.

Non-Clinical Performance Data:

Design verification and validation of the modified device was done with conformance to or evaluated based on the following FDA guidance:

Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents, February 5, 1998.

All test results confirm the modified device to be substantially equivalent to the predicate device.

Conclusions:

The Bard® E•LUMINEXX™ Biliary Stent met all the predetermined performance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. Bard® E•LUMINEXX™ Biliary Stent is substantially equivalent to the legally marketed predicate device, the Bard® LUMINEXX® 3 Biliary Stent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lindsay Pack
Senior Regulatory Affairs Specialist
Bard Peripheral Vascular, Inc.
1625 West 3rd Street
P.O. Box 1740
TEMPE ARIZONA 85280-1740

MAY 30 2008

Re: K063532
Trade/Device Name: Bard® E•LUMINEXX® Biliary Stent
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: March 4, 2008
Received: March 6, 2008

Dear Ms. Pack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063532

Device Name: Bard® E•LUMINEXX® Biliary Stent

FDA's Statement of the Indications For Use for device:

The proposed device is indicated for the treatment of biliary strictures resulting from malignant neoplasms.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K063532